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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,996	11/15/2001	Peter M. Bonutti	BON-1360-8	8298

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EXAMINER	
HOFFMAN, MARY C	

ART UNIT	PAPER NUMBER
3733	

MAIL DATE	DELIVERY MODE
06/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/003,996	BONUTTI, PETER M.	
	Examiner	Art Unit	
	MARY HOFFMAN	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-44,46,47,49,51-55,57-60 and 69-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *36-44,46,47,49,57-60 and 69-76* is/are allowed.

6)☒ Claim(s) *51-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 53-55 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Leary (U.S. Patent No. 5,073,373) in view of Kambin (U.S. Patent No. 4,573,448) and Wiley (U.S. Patent No. 4,083,706)

O'Leary discloses A surgical procedure to be conducted on a patient, said surgical procedure comprising the steps of inserting a first tubular member into a patient's body, moving body tissue from a first location in the patient's body through the first tubular member to a location outside of the patient's body, inserting a second tubular member into a second patient's body, and moving at least a portion of the body tissue through the second tubular member to a second location in the second patient's body, wherein a substance is added to the body tissue after moving the body tissue from the first location through the first tubular member to a location outside of the patient's body and prior to moving the body tissue through the second tubular. {O'Leary discloses using allogenic bone}

O'Leary discloses the claimed invention except for the body tissue being re-implanted into the same patient, i.e. using autogenic bone, and the first tubular member used to cut the tissue from the sterile trap.

First of all, it would have further been obvious to use autogenic bone (meaning that the bone is taken from the patient and then re-implanted into the patient) rather than allogenic bone since the Supreme Court has recently found that where there is a "design need or market pressure and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense." *KSR v. Teleflex*, 550 U.S. _ (2007). The design need for autogenic bone is due to the well-known need for compatible bone with a patient's tissue, and it is well know that autogenic bone provides optimum compatibility with the patient's body since it is originally from the patient. Also, clearly, a finite number of solutions (autogenic, allogenic, or xenogenic bone) exist. Therefore, it would have been obvious to one of ordinary skill in the art to substitute allogenic with autogenic bone.

Wiley teaches that when doing an autogenic transplant, a sterile trap is used (see Column 1, lines 22-26).

Kambin teaches a tissue-cutting instrument that provides a rotatable cutter and suction (Column 3 lines 47-56).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of O'Leary using the sterile trap of Wiley,

which is used for autogenic transplants, and with the cutter of Kambin since Kambin's cutter is used to remove tissue fragments, which can be modified in the method of O'Leary which cuts and removes tissue fragments in order to make the desired bone paste.

Claims 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Leary ' 373 in view of Kambin '448 and Wiley '706 as applied above, and further in view of Muller-Lierheim (U.S. Patent No. 4,828,563) and Amrani (U.S. Patent No. 4,210,580).

O'Leary, as modified, discloses the closed invention except for centrifuging the blood or body tissue to separate one or more components from the blood.

Muller-Leirheim teaches that growth factors, particularly fibronectin, are added to bone implants to enhance biocompatibility and mechanical strength (Column 1 line 37-Column 2 line 7). Amrani teaches that fibronectin may be obtained from blood plasma by centrifuging the blood plasma (Column 2 lines 26-30).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of O'Leary with the additional step of centrifuging blood to obtain fibronectin in view of Muller-Leirheim and Amrani, an additive to an implant material, to enhance the biocompatibility and strength of the O'Leary implant material.

Response to Arguments

Applicant's arguments filed 03/04/2008 have been fully considered but they are not persuasive.

As stated above, it would have further been obvious to use autogenic bone (meaning that the bone is taken from the patient and then re-implanted into the patient) rather than allogenic bone since the Supreme Court has recently found that where there is a "design need or market pressure and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense." *KSR v. Teleflex*, 550 U.S. _ (2007). The design need for autogenic bone is due to the well-known need for compatible bone with a patient's tissue, and it is well know that autogenic bone provides optimum compatibility with the patient's body since it is originally from the patient. Also, clearly, a finite number of solutions (autogenic, allogenic, or xenogenic bone) exist. Therefore, it would have been obvious to one of ordinary skill in the art to substitute allogenic with autogenic bone. Regarding using a sterile trap, it would have been obvious to use such as device when using autogenic tissue.

The rejections are deemed proper.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary C. Hoffman/
Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733